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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/937,839 | 02/21/2002 | Yasufumi Kaneda | 59150.8010 | 7050 |

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| EXAMINER | |
|---|---|
| WHITEMAN, BRIAN A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | |

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/937,839 | KANEDA, YASUFUMI | |
| | Examiner | Art Unit | |
| | Brian Whiteman | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10,15,17,19,23,34-36* is/are allowed.

6)☒ Claim(s) *1-9,11-14,16,18,20-22 and 24-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### Final Rejection

Claims 1-36 are pending examination.

Applicants' traversal, the sequence listing, the amendment to the specification, and the amendment to the claims 1-16, 18, 20, and 21 in paper filed 12/9/03 is acknowledged and considered.

### *Drawings*

The drawings were received on 12/9/03. These drawings are acceptable.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11-14, 18, 20-22, 24-29, and 31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoon et al. (US Patent 6,472,375). Hoon teaches a viral liposome vector comprising fused HVJ, which contains a viral envelope, with nonviral reagents for delivery of nucleic acid encoding a tumor-associated antigen into a tumor or an organ (column 3, lines 5-9, column 13, line 29, and Fig. 1). Hoon further teaches a pharmaceutical composition or a kit comprising the viral liposome vector (column 2, lines 65-67 and column 3, lines 20-22).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant's arguments filed 12/9/03 have been fully considered but they are not persuasive. Applicant cites an excerpt from MPEP 2131 and argues that Hoon fails to teach a method for introducing a gene into isolated animal comprising a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope. See page 15.

NOTE: Applicants state that only claims 18 and 31-33 are rejected over Hoon et al., however, as stated in the prior office action mailed on 4/29/03, claims 1-9, 11-14, 20-22, and 24-29 were also rejected over Hoon.

With respect to applicant's argument, the argument is not found persuasive because as set forth above Hoon anticipates the claimed invention. The vector taught by Hoon is a viral liposome vector with a viral envelope. The virus envelope is a native virus envelope because; absence evidence to the contrary, the envelope was not modified or replaced by Hoon. See Figure 1. Therefore, other than applicant citing an excerpt from MPEP 2131 and asserting that Hoon does not teach a vector having a **native** virus envelope, the applicant does not provide sufficient evidence to support the assertion. Also see MPEP § 716.01(c).

MPEP 2112.01 recites: Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially

identical processes, a prima facie case of either **anticipation** or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). This is the case here. Hoon teaches the gene transfer vector.

Claims 1-9, 11-12, 16, 18, 20-22, 30, 31, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramani et al. (PNAS, 95:11886-18890, 1998). Ramani teaches a F-virosomes (Sendai virus) containing pCIS3CAT or pBVluc DNA (page 11886). The plasmid was incubated with detergent solubilized fraction of Sendai virus containing its envelope. Ramani further teaches delivering the F-virosomes to a liver in mice (abstract).

Applicant's arguments filed 12/9/03 have been fully considered but they are not persuasive.

Applicant argues that Raimani fail to teach a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope. Raimani further fails to teach a method of making a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope or using the vector to introducing a gene into animal tissue.

With respect to applicant's argument, the argument is not found persuasive because as set forth above Ramani anticipates the claimed invention. The vector taught by Ramani is a viral liposome vector with a viral envelope. The virus envelope is a native virus envelope because; absence evidence to the contrary, the envelope was not modified or replaced by Ramani. See page 11886, Materials and Methods. Therefore, other than the applicant citing an excerpt from MPEP 2131 and asserting that Ramani does not teach a vector having a **native** virus envelope, the applicant does not provide sufficient evidence to support the assertion. Also see MPEP § 716.01(c).

MPEP 2112.01 recites: Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either **anticipation** or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). This is the case here.

NOTE: The authors of the article are Ramani et al. and not Raimani et al. as stated by applicants.

***Response to Arguments***

Applicant's arguments, filed 12/9/03, with respect to objection have been fully considered and are persuasive. The objection of claims 2-12 and 20-21 has been withdrawn because of the amendment to the claims. See page 12.

Applicant's arguments, filed 12/9/03, with respect to 112 first paragraph written description rejection have been fully considered and are persuasive. The rejection of claims 1, 13-16, 18-19 and claims dependent therefrom has been withdrawn because of the amendment to the independent claims to remove the term "membrane." See page 12.

Applicant's arguments, filed 12/9/03, with respect to 112 first paragraph enablement rejection have been fully considered and are persuasive. The rejection of claims 1, 13-16, 18-19 and claims dependent therefrom has been withdrawn because of the amendment to the independent claims to remove the term "membrane." See page 12.

Applicant's arguments, filed 12/9/03, with respect to 112 second paragraph have been fully considered and are persuasive. The rejection of claims 1, 13-16, 18-19 and claims

dependent therefrom has been withdrawn because of the amendment to the independent claims to remove the term "membrane." See page 12.

***Conclusion***

Claims 10, 15, 17, 19, 23, and 34-36 are in condition for allowance because the claims are free of the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER